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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/573,385 | 05/07/2007 | Tomoki Hamamoto | 2006_0434A | 9339 |

513 7590 05/04/2011
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| EXAMINER |
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EPPS -SMITH, JANET L

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| ART UNIT | PAPER NUMBER |
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1633

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| NOTIFICATION DATE | DELIVERY MODE |
|-------------------|---------------|

05/04/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ddalecki@wenderoth.com
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| | | | |
|------------------------------|---|--|--|
| Office Action Summary | Application No. 10/573,385 | Applicant(s) HAMAMOTO ET AL. | |
| | Examiner JANET L. EPPS -SMITH | Art Unit 1633 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,7,9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,7,9 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 5, 7, and 9-10 are presently pending for examination.

Response to Arguments

Claim Rejections - 35 USC § 112

3. The rejection of claims 1-2, 4-5, 7, and 9-10 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in response to Applicant's amendment to the claims.

Claim Rejections - 35 USC § 103

4. Applicant's arguments with respect to the rejection of claims 1-10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Simon et al. in view of Warren et al. and Vann et al. are moot in view of the new grounds of rejection set forth below.
5. Claims 1, 5, 7, and 9-10 are rejected under 35 USC 103(a) as being unpatentable over Kittlemann et al. US (5,334,514) in view of Prieto et al. US (5,945,314).
6. The instant claims are drawn to a process for the purification of CMP-N-acetylneuraminic acid without the employment of any chromatography treatment, comprising adding calcium or manganese ion to a CMP-NeuAc-containing solution, adding a phosphatase to the solution, adding an alcohol having a carbon number of 5 or

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less, and collecting the precipitated CMP-NeuAc, the sequence of the steps are as set forth in the claims, and further wherein the purity is measured by HPLC.

7. Kittlemann et al. describes the following method:

“The reaction of the sialic acids, e.g. Neu5Ac, with CTP in the presence of the microbial cell extract is preferably carried out in homogeneous aqueous solution in the presence of approximately from 10-50, especially approximately from 20-40 mM Mg.sup.2+, e.g. in the form of a corresponding halide or sulfate, e.g. MgCl.sub.2 or MgSO.sub.4, or in the presence of approximately from 5-30, especially approximately from 10-15 mM Mn.sup.2+, e.g. in the form of a corresponding halide or sulfate, such as MnCl.sub.2 or MnSO.sub.4. The pH value of the reaction mixture is, in the presence of Mg-ions, adjusted to approximately 8-11, preferably 8-10, and, in the presence of Mn-ions, to approximately 6-8, preferably 7.5, and, for the stabilisation of the pH value, the reaction is carried out in a manner known per se in buffered solution or using a pH-stat. The reaction temperature is approximately from 20°C-35°C., preferably approximately from 25-30°C. The reactants are used preferably in equimolar amounts.”

“[S]uch naturally occurring microorganisms having CMP-Neu5Ac synthetase activity can be converted in a manner known per se by mutation, for example using generally known mutagens, such as UV-rays or X-rays, or mutagenic chemicals, into mutants that are differentiated from their parents by improved properties, e.g. lower nutrient medium demands, higher growth rates and, especially, higher CMP-Neu5Ac synthetase activity. Such mutants can also occur spontaneously. The identification and isolation of such

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mutants is carried out also in a manner known per se: the CMP-Neu5Ac-synthetase activity of colonies of such mutants is ascertained, for example, after disintegration of the cells, by adding specific amounts of CTP and Neu5Ac to aliquot portions of the cell residue and qualitatively or quantitatively determining the CMP-Neu5Ac that has formed by means of chromatography, especially HPLC. “

The method of Kittlemann et al. does not comprise the use of an alcohol of 5 carbons or less. However, the CMP-NeuAc purification method of Prieto et al. comprises the following:

The resulting solution is then lyophilized, or in the alternative, lyophilized and subjected to evaporation from ethanol or methanol to obtain purified sugar-nucleotides.

Absent evidence of unexpected results, it would have been obvious to modify the method of Kittlemann et al., which does not require a chromatographic separation, with the purification via ethanol or methanol method of Prieto et al. One of ordinary skill in the art would have had a reasonable expectation of success in combining the two methods to produce the claimed invention since both prior art methods do not require a chromatographic purification step, and both are directed to the purification of CMP-NeuAc.

As stated in a previous Office Action, in regards to Applicant's assertions regarding the high purity produced by the claimed methods, Applicants have not provided any evidence to support their assertion of unexpectedly high purity of CMP-NeuAc commensurate in scope with the entire breadth of the claimed invention, particularly regarding the use of any alcohol source of 5 carbons or less. As per MPEP

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§ 716.01(c)[R-2]II, “[T]he arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant.”

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

9. The new ground of rejection as set forth above was necessitated by Applicant's amendment.

10. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JANET L. EPPS -SMITH whose telephone number is (571)272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/
Primary Examiner, Art Unit 1633